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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,094

10/22/2004

Abdurrahman Mithat Bozdayi

BJS-2551-158

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08/22/2008

NIXON & VANDERHYE, PC

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ARLINGTON, VA 22203

EXAMINER

KINSEY WHITE, NICOLE ERIN

ART UNIT

PAPER NUMBER

16-48

MAIL DATE

DELIVERY MODE

08/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/509,094

Applicant(s)BOZDAYI, ABDURRAHMAN
MITHAT**Examiner**

NICOLE KINSEY WHITE

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37-40 is/are pending in the application.
- 4a) Of the above claim(s) 31-35 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 8-16 and 21-24 is/are rejected.
- 7) ☒ Claim(s) 3, 7, 17-20, 25-30 and 38-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Withdrawn Rejections

The rejection of claims 17-20, 25-30, 38 and 39 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of applicants' amendments to the claims.

Claim Objections

Claim 40 is objected to because of the following informalities: Claim 40 is missing the word "and" between (ii) and (iii). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-16 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting the presence of HBV in a sample by detecting polynucleic acid comprising the reverse transcriptase domain with a mutation at codon 204, wherein codon 204 is a serine, does not reasonably provide enablement for detecting the presence of HBV in a sample by detecting an HBV polynucleic acid or fragment comprising codon 204 of the reverse transcriptase domain, wherein codon 204 is a serine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a method (and a kit) for detecting the presence of a HBV in a biological sample, by detecting the presence of an HBV polynucleic acid or fragment comprising codon 204 (serine) of the HBV reverse transcriptase domain.

The claims, as written, read on a trinucleotide that encodes serine (i.e., a fragment that comprises codon 204 (serine)) and read on other non-reverse transcriptase HBV proteins that contain a serine (i.e., an HBV polynucleic acid that contains serine 204 from HBV reverse transcriptase).

According to the specification, an isolated HBV reverse transcriptase domain nucleic acid or polypeptide can be used to detect a variant HBV in a sample by determining if codon 180 of the domain is a methionine and/or codon 204 of the domain is a serine. However, there is no teaching in the specification that a fragment of any size (e.g., a trinucleotide encoding serine) or a non-reverse transcriptase HBV protein that contains serine 204 from reverse transcriptase can be used to detect a variant HBV in a sample.

Given the breadth of the claims and the lack of guidance in the specification, the full scope of the method and kit claims is not enabled.

Response to Arguments

In the reply dated June 3, 2008, applicants amended the claims to delete the phrase "or fragment thereof", which addressed the "fragment" part of the rejection. However, the reply did not address how non-reverse transcriptase HBV proteins (and nucleic acids) that contain serine 204 from reverse transcriptase can be used to detect a variant HBV in a sample. The claims, as written, include any HBV proteins that

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contain a serine (i.e., that contain residue 204 from HBV reverse transcriptase) at any position.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, 8-12, rejected under 35 U.S.C. 102(b) as being anticipated by Petzold et al. (GenBank Accession No. AJ131956, Submitted 05-JAN-1999).

The claims are drawn to an isolated HBV polynucleic acid or a fragment thereof, said polynucleic acid or said fragment comprises codon 204 of the HBV reverse transcriptase domain, wherein said codon 204 encodes a serine. The HBV polynucleic acid or fragment can further comprise codon 180 of the HBV reverse transcriptase domain, wherein said codon 180 encodes a methionine.

Petzold et al. discloses an HBV polynucleic acid (and polypeptide) for the surface antigen, said nucleic acid (and polypeptide) contains codon 180 (methionine) and codon 204 (serine) from HBV reverse transcriptase.

Response to Arguments

In the reply dated June 3, 2008, applicants argue that Petzold et al., which discloses YMDD instead of YSDD, does not anticipate the claims.

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The claims are directed to an isolated HBV polynucleic acid, said polynucleic acid characterized in that it comprises codon 204 of the HBV reverse transcriptase domain, wherein said codon 204 encodes a serine. The HBV polynucleic acid or fragment can further comprise codon 180 of the HBV reverse transcriptase domain, wherein said codon 180 encodes a methionine.

The claims read on any HBV polynucleic acid that contains codon 204 from the HBV reverse transcriptase domain. In other words, any HBV polynucleic acid that contains serine will anticipate the claimed invention. Petzold et al. discloses such a nucleic acid.

Claims 3, 7, 17-20, 25-30 and 38-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White, PhD/
Examiner, Art Unit 1648

/Stacy B. Chen/
Primary Examiner, Art Unit 1648

Application Number**Application/Control No.**

10/509,094

**Applicant(s)/Patent under
Reexamination**BOZDAYI, ABDURRAHMAN
MITHAT**Examiner**

NICOLE KINSEY WHITE

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1648